

COHN LIFLAND PEARLMAN
HERRMANN & KNOPF, LLP
PETER S. PEARLMAN
Attorneys for Plaintiff
Park 80 Plaza West One
Saddle Brook, New Jersey 07663
(201) 845-9600
Liaison Counsel

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

"DOCUMENT ELECTRONICALLY FILED"

**IN RE REMERON DIRECT PURCHASER
ANTITRUST LITIGATION**

Master Docket No. 03-CV-0085 (FSH)

**THIS DOCUMENT RELATES TO:
ALL ACTIONS**

**MEMORANDUM OF LAW IN SUPPORT OF DIRECT PURCHASER CLASS
PLAINTIFF'S MOTION FOR PRELIMINARY APPROVAL OF PROPOSED
SETTLEMENT, CERTIFICATION OF THE PROPOSED CLASS IN LIGHT OF
SETTLEMENT, APPOINTMENT OF CLASS COUNSEL AND
APPROVAL OF THE FORM AND MANNER OF NOTICE TO THE CLASS**

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Louisiana Wholesale Drug Co., Inc. ("Plaintiff") respectfully submits this Memorandum of Law in support of Plaintiff's Motion for Preliminary Approval of Proposed Settlement, Certification of the Proposed Class in Light of Settlement, Appointment of Class Counsel and Approval of the Form and Manner of Notice to the Class.

After completion of discovery and two extensive mediations, Plaintiff and Defendants Organon USA Inc. and Akzo Nobel N.V. (collectively, "Defendants") have entered into a proposed settlement providing for the payment of \$75 million in cash to Plaintiff and members of the Class (the "Settlement"), in exchange for dismissal of this litigation with prejudice and certain releases from the Class fully set forth in the Settlement Agreement. This is an excellent result achieved after more than two years of litigation and the conclusion of merits discovery.

Plaintiff now seeks certification of the Class in light of the proposed Settlement, preliminary approval of the proposed Settlement and requests that the Court set in motion the process to determine whether final approval of the Settlement should be granted, after notice to the Class, and a subsequent hearing on final approval ("Fairness Hearing").¹ This motion for preliminary approval is unopposed by Defendants.

I. BACKGROUND

This Class Action² was brought by direct purchasers of the drug Remeron® from Defendants

¹ As detailed below, preliminary approvals of proposed class action settlements are procedural in nature and do not involve determinations on the merits of the proposed settlement, as long as the settlement falls within the range of possible approval. See In re Prudential Securities Inc. Ltd. P'ships Litig., 163 F.R.D. 200, 209 (S.D.N.Y. 1995).

² The Class Action consolidated the cases Louisiana Wholesale Drug Co., Inc. v. Organon, Inc. et al., No. 2:03-00323-FSH (D.N.J. 2003) and Meijer, Inc. v. Organon, Inc. et al., No. 2:03-00085-FSH (D.N.J. 2003).

(the “Direct Purchaser Class” or “Class”), as defined below. Among other things, Plaintiff has claimed that Defendants violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by allegedly (1) using various illegal and deceptive means as part of an overall scheme to improperly create and extend patent protection for the drug Remeron® by manipulating the Hatch-Waxman statutory scheme; (2) committing affirmative misrepresentations and failing to disclose material prior art in the prosecution of U.S. Patent No. 5,977,099 (the “‘099 Patent”) before the United States Patent Office; (3) making false and misleading representations to the Food and Drug Administration (“FDA”) to obtain the listing of the ‘099 patent in the FDA’s Orange Book³ in a wrongful manner; (4) submitting the ‘099 patent for listing in the Orange Book approximately 14 months beyond the FDA-mandated deadline for patent listing; and (5) filing and prosecuting sham patent litigation against generic competitors. Plaintiff alleges that Defendants’ conduct delayed the market entry of less expensive generic versions of Remeron®, thereby forcing members of the Direct Purchaser Class to pay artificially inflated prices for both Remeron® and/or its AB-rated generic equivalents.

Defendants deny each and every one of Plaintiffs allegations of unlawful or improper conduct, deny Plaintiff’s and the Class’s entitlement to damages or any other relief, and assert several defenses. Defendants argue that Plaintiff has failed to state a claim upon which the Court can grant relief, that Defendants acted in furtherance of their legitimate business interests and have caused no injury to competition, the public, or Plaintiff, that Defendants’ conduct was protected by the First Amendment to the U.S. Constitution, and that Defendants’ conduct was otherwise lawful.⁴

³ The “Orange Book” is an official FDA publication formally known as “Approved Drug Products With Therapeutic Equivalence Evaluations.”

⁴ On September 8, 2004, the Court dismissed certain antitrust causes of action asserted by direct purchaser plaintiffs. See In re Remeron Antitrust Litig., 335 F. Supp. 2d 522 (D.N.J. 2004).

The proposed Settlement was reached after intensive arm's-length negotiations, multiple mediation sessions held with both the aid of the Court and two skilled mediators, substantial fact and expert discovery including, among other things, the production and inspection of over one million pages of documents, numerous depositions of Defendants' employees and third-party witnesses, substantial briefing on the legal issues (including class certification and summary judgment), consultation with economic, scientific and medical experts regarding numerous relevant legal, evidentiary and economic issues (including, for instance, estimating damages incurred by the Class), rulings of the Court on a number of legal claims and issues, and successfully defeating, in part, Defendants' motion to dismiss.

The proposed Settlement Agreement, which is attached to the Certification of Peter S. Pearlman submitted in support of the instant motion for preliminary approval (the "Certification") as Exhibit "A", provides for a cash payment of \$75 million to Plaintiff and the Class in exchange for dismissal of the litigation with prejudice and certain releases from the Class fully set forth in paragraph 11 of the Settlement Agreement.⁵

The Federal Rules of Civil Procedure provide that the approval of a class action settlement

On February 18, 2005, the Court denied Plaintiff's motion for summary judgment directed at issues of monopoly power and market definition. See In re Remeron Direct Purchaser Antitrust Litig., 367 F. Supp. 2d 675 (D.N.J. 2005). A motion for summary judgment in favor of Defendants was pending at the time the Settlement was reached.

⁵ As provided in paragraph 12 of the Settlement Agreement, these releases specifically exclude (i.e. do not release) any claims arising in the ordinary course of business between Class members and the Released Parties (as defined in paragraph 11 of the Settlement Agreement) concerning product liability, breach of contract, breach of warranty, or personal injury, other than any such claim based in whole or in part on any conduct challenged by any plaintiff, or on the operative facts alleged, in the Class Action or in any action or proceeding coordinated or consolidated in Master Docket No. 2:03-cv-0085-FSH-PS.

follow several steps. The step contemplated by this particular motion is the submission of the proposed Settlement to the Court for preliminary approval and then communication of the terms of the proposed Settlement to the Class for its consideration. If the Court grants the instant motion, the terms of the proposed Settlement will be communicated to the Class through Court-approved form of notices to be sent directly to Class members by United States mail and printed in a publication likely to reach all or substantially all Class members. Organon has reviewed and agreed to the proposed forms of notice. The proposed forms of notice are attached to the Settlement Agreement as Exhibit "B" (direct mail notice and publication notice). Mail and publication notice in the manner described and in the form attached to the Settlement Agreement constitute the proposed notice plan for the Settlement.

The instant motion, accordingly, seeks entry of the proposed Preliminary Approval Order attached to the Settlement Agreement as Exhibit A, which provides for: (i) preliminary approval of the proposed Settlement by the Court; (ii) certification of the Class and appointment of Class counsel; (iii) approval of the proposed form and manner of notice; and, (iv) approval of the proposed schedule leading up to and including the Fairness Hearing.

II. THE COURT SHOULD CERTIFY THE PROPOSED CLASS AND APPOINT CLASS COUNSEL

The proposed Settlement contemplates the certification of a Class defined as:

All persons or entities (and assignees of claims from such persons or entities) who directly purchased Remeron® from Defendants at any time during the period of January 16, 2002 through the date of the Settlement Agreement (the "Class Period"). Excluded from the Class are the defendants in this lawsuit, and their officers, directors, management and employees, subsidiaries and affiliates.

Also excluded from the Class are, to the extent they would otherwise be in this Class, either as a direct purchaser or as an assignee of a direct purchaser, Walgreen Co., Eckerd Corporation, Albertson's, Inc., The Kroger Co., American Sales Company, Safeway, Inc., Hy- Vee, Inc., CVS Meridian, Inc., and Rite Aid Corporation, and their successors in interest, who initiated the actions styled CVS Meridian, Inc., et al. v. Organon, Inc., et al., No. 2:03-cv-05488-FSH-PS, and Walgreen Co., et al. v. Organon, Inc., et al., No. 2:03-cv-02221-FSH-PS, which have been dismissed with prejudice; and to the extent they would otherwise be in this Class, either as a direct purchaser or as an assignee of a direct purchaser, the 50 states of the United States of America, the District of Columbia, the Commonwealth of Puerto Rico, and the possessions and territories of the United States of America, who initiated the action styled State of Oregon et al. v. Organon USA Inc., et al., No. 2:04-cv-05126-FSH-PS, which has been dismissed with prejudice as of the date this Settlement becomes final in accordance with its terms.

This motion for preliminary approval asks that the Court certify the Class.⁶ For purposes of class certification, the Court should not engage in a determination of the merits. See, e.g., Eisen v. Carlisle & Jacquelin, 417 U.S. 156, 177-78 (1974) (determination of class certification should not become a trial on the merits); In re Fine Paper Antitrust Litig., 82 F.R.D. 143, 149 (E.D. Pa. 1979). While certification of a class at the time of settlement alleviates the need for the Court to inquire into

⁶ As provided in paragraph 1 of the Settlement Agreement, the Defendants have stipulated to class certification in light of the proposed Settlement "only for purposes of effectuating [the] Settlement, and for no other purpose." Should the Settlement not become final pursuant to its terms, this stipulation will be null and void, and Defendants will retain "all of their . . . arguments and/or defenses with respect to class certification." Id. Plaintiff's points and authorities in favor of class certification presented herein are unopposed by Defendants in light of, and subject to, the terms of the Settlement Agreement.

the issue of whether the case, if tried, would present intractable management problems, the proposed Class must still meet most of the requirements of Fed. R. Civ. Pro. 23. See Amchem Prods., Inc. v. Windsor, 521 U.S. 591, 620 (1997) (“Amchem”). The proposed Class here easily satisfies each requirement of Rule 23(a) (numerosity, commonality, typicality, and adequacy of representation), as well as the requirements of Rule 23(b)(3).⁷

A. The Requirements of Rule 23(a) Are Satisfied

1. *Numerosity*

Under Fed. R. Civ. P. 23(a)(1), Plaintiff must only demonstrate that the proposed class is so numerous that joinder is impracticable; the rule does not require impossibility and does not require precise enumeration of class size. See Lerch v. Citizens First Bancorp, Inc., 144 F.R.D. 247, 250 (D.N.J. 1992). As the Third Circuit has observed, “[n]o minimum number of plaintiffs is required to maintain a suit as a class action, but generally if the named plaintiff demonstrates that the potential number of plaintiffs exceeds 40, the first prong of Rule 23(a) has been met.” Stewart v. Abraham, 275 F.3d 220, 227-28 (3d Cir. 2001).

Here, nearly identical in composition and size to the classes certified in similar antitrust actions involving delayed generic competition,⁸ the Class consists of all entities that directly

⁷ The question of class certification in this case has been extensively briefed before this Court in connection with Plaintiff’s Motion for Class Certification, filed on October 27, 2004. Plaintiff respectfully refers the court to Direct Purchaser Class Plaintiffs’ Memorandum of Law in Support of Their Motion for Class Certification (“Class Brf.”), filed in support of that motion for a detailed application of the Rule 23 standard to the proposed Class, complete with record evidence and the report of Plaintiff’s expert economist. For purposes of the instant motion, the points and authorities presented in Plaintiff’s earlier motion will be summarized here.

⁸ See, e.g., In re Buspirone Patent Litig., 210 F.R.D. 43 (S.D.N.Y. 2002) (“Buspirone”); In re Cardizem CD Antitrust Litig., 200 F.R.D. 297 (E.D. Mich. 2001) (“Cardizem”); In re Relafen Antitrust Litig., 218 F.R.D. 337 (D. Mass. 2003) (“Relafen”).

purchased Remeron® from Defendants over a period extending from January 16, 2002 through and including August 24, 2005. Jeffrey J. Leitzinger, Ph.D., an economist submitting a Declaration in support of class certification, estimates the number of class members at more than 50 geographically dispersed entities. See Class Brf at 10. Compare Buspirone, 210 F.R.D. at 57 (possibly over 100 direct purchasers of brand-name drug); Cardizem, 200 F.R.D. at 303 (80 direct purchasers of brand-name drug); In re Mercedes-Benz Antitrust Litig., 213 F.R.D. 180, 184 (D. N.J. 2003) (“Mercedes”) (90 class members). The numerosity requirement is therefore satisfied.

2. *Commonality*

Common questions of law and fact are routinely found in an antitrust case alleging anticompetitive conduct, because class members necessarily use the same evidence to prove their allegations of improper maintenance of a monopoly. In fact, the very nature of antitrust cases such as that instantly, brought under § 2 of the Sherman Act, has led courts almost uniformly to find that commonality exists. See, e.g., Buspirone, 210 F.R.D. at 57; Jennings Oil Co., Inc. v. Mobil Oil Corp., 80 F.R.D. 124, 128 (S.D.N.Y. 1978) (“The monopolization claims are contingent upon a showing of monopoly power and an examination of the manner in which such power was acquired or maintained. . . . These issues, along with others, are questions that are undoubtedly common to all the members of the putative class”) (citation omitted). See also In re Linerboard Antitrust Litig., 203 F.R.D. 197, 205-06 (E.D. Pa. 2001), (“[c]ourts interpreting the commonality requirement in the antitrust area have held that allegations concerning the existence, scope and efficacy of an alleged conspiracy present questions adequately common to class members to satisfy the commonality requirement”) aff’d 305 F.3d 145 (3d Cir. 2002).

Here, Plaintiff has presented abundant proof of common issues of law and fact in the instant

case.⁹ Rule 23(a)(2) is clearly satisfied here.

3. *Typicality*

Rule 23(a)(3) requires that “the claims . . . of the representative parties [be] typical of the claims . . . of the class.” “Typicality lies where there is a strong similarity of legal theories, or where the claims of the representative plaintiffs and the rest of the class arise from the same alleged conduct by the defendants.” Mercedes, 213 F.R.D. at 185 (citation omitted). However, “[t]ypicality does not require that the claims of the named plaintiffs be identical to those of the proposed class members.” Id.; see also Class Brf. at 11–12.

In this case, all Class members’ claims arise out of a common alleged wrong: a pattern of alleged anticompetitive conduct that, if true, would have similarly injured each of them by artificially raising or stabilizing the price of mirtazapine. See, e.g., Amended Complaint, In re Remeron Direct Purchaser Antitrust Litig., No. 03-0085 (D.N.J. 2003) (FSH) (“Amend. Comp.”) at ¶¶ 70-72, 81-83. Where, as here, the Class challenges Defendants’ alleged anticompetitive conduct and seeks monetary recovery for artificially inflated prices, typicality is easily established. See In re Sugar Indus. Antitrust Litig., 73 F.R.D. 322, 336 (E.D. Pa. 1976) (typicality met in antitrust action because

⁹ Common questions of law and fact presented by Plaintiff included, for instance: (1) whether Defendants intentionally blocked and/or delayed market entry of various competitors’ less expensive generic mirtazapine; (2) whether the ‘099 Patent claimed an FDA-approved drug product and an approved method of using Remeron®; (3) whether any reasonable basis existed for listing the ‘099 Patent in the Orange Book; (4) whether any reasonable basis existed for Defendants’ patent infringement litigation against various would-be sellers of generic mirtazapine; (5) whether Defendants’ conduct violated § 2 of the Sherman Act; (6) whether, and to what extent, Defendants possessed and/or maintained monopoly power; (7) whether Defendants’ conduct caused antitrust injury to the business or property of Plaintiffs and the members of the Class and, if so, the appropriate measure of damages; and (8) whether, but-for Defendants’ conduct, Class members would have begun benefitting from lower-priced generic mirtazapine much sooner than they actually did. See Class Brf. at 10 – 11.

each class representative and absent class member seeks to prove same ultimate facts); Mercedes, 213 F.R.D. at 185 (same). For this reason, typicality was readily established in three virtually identical antitrust cases alleging overcharges in the purchase of pharmaceutical products due to delayed generic entry. See Buspirone, 210 F.R.D. at 57; Relafen, 218 F.R.D. at 343; Cardizem, 200 F.R.D. at 304-05.

4. *Adequacy of Representation*

In this Circuit, “[a]dequate representation depends on two factors: (a) the plaintiff’s attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class.” Wetzel v. Liberty Mut. Ins. Co., 508 F.2d 239, 247 (3d Cir.), cert. denied, 421 U.S. 1011 (1975). A single adequate representative plaintiff suffices, even if more than one is proffered. See Jerry Enters. of Gloucester County, Inc. v. Allied Beverage Group, L.L.C., 178 F.R.D. 437, 446 n.5 (D.N.J. 1998) (“Jerry Enterprises”). As the very same class representative, and the very same counsel, have been held by other courts to satisfy the adequacy prong of Rule 23(a) in closely similar cases, the adequacy requirement is clearly satisfied here.¹⁰

a. Absence of Conflict

There are no actual or potential conflicts between the proposed Class representative and the absent Class members. Each Class member has the same interest as the Class representative in

¹⁰ See, e.g., Buspirone, 210 F.R.D. at 58 (same plaintiff (LWD) and same class counsel); Cardizem, 200 F.R.D. at 305-07 (same plaintiff (LWD) and same counsel); Relafen, 218 F.R.D. at 343– 344 (same plaintiff (LWD) and same class counsel) Oncology & Radiation Assoc., P.A. v. Bristol-Myers Squibb Co., No. 01-CV-2313, 2003 WL 21087979 (D. D.C. May 13, 2003) (“Taxol”) (same class counsel). LWD successfully performed the function of representative plaintiff through prosecution and settlement of the Buspirone, Cardizem and Relafen cases.

establishing Defendants' liability. Defendants' anticompetitive conduct is alleged to have (1) deprived every Class member of the opportunity to satisfy some or all of its mirtazapine requirements with a lower-priced generic alternative, and (2) forced every Class member to pay artificially inflated prices for mirtazapine. See, e.g., Amend. Comp. ¶¶ 82-83; see also Relafen, 218 F.R.D. at 345; Buspirone, 210 F.R.D. at 58-59. By pursuing this litigation on their behalf, Plaintiff has necessarily advanced the common interests of the entire Class.¹¹

b. Qualifications of Counsel

With regard to the adequacy of counsel, "firm resumes [demonstrating that plaintiffs' counsel] possess the competence, skill, and experience necessary to the prosecution of the class claims" suffice. Jerry Enterprises, 178 F.R.D. at 446. This standard is met. Plaintiff's counsel have extensive experience and expertise in antitrust, class action, and complex civil litigation, and have successfully prosecuted antitrust class actions and other similar cases in courts throughout the United States. Indeed, many of the Class counsel here are involved in prosecuting a number of substantively similar antitrust actions alleging the delay of generic competition in other brand-generic drug markets, which are currently pending or recently successfully settled.¹²

¹¹ As between and among the Class representative and absent Class members, neither differing sales volumes and purchases, nor speculative conflicts, can defeat a finding of adequacy of representation. See In re Flat Glass Antitrust Litig., 191 F.R.D. 472, 482-83 (W.D. Pa. 1999); Jerry Enterprises, 178 F.R.D. at 442-45; Cardizem, 200 F.R.D. at 305-06; In re NASDAQ Market-Makers Antitrust Litig., 169 F.R.D. 493, 513-14 (S.D.N.Y. 1996) ("NASDAQ").

¹² Co-Lead Counsel for the Direct Purchaser Class (Garwin Gerstein & Fisher LLP and Cohen Milstein Hausfeld & Toll, PLLC), and the other firms acting as class counsel, have also been involved in prosecuting similar antitrust class actions involving anti-competitive conduct in the pharmaceutical industry allegedly resulting in delayed entry of generic drugs. See, e.g., Relafen, Master File No. 01-12239-WGY (D. Mass.) (Young, C.J.); Buspirone, No. 01-MDL-1413 (S.D.N.Y.) (Koeltl, J.); Cardizem, No. 99-MDL-1278 (E.D. Mich.) (Edmunds, J.); Terazosin, No. 99-MDL-1317 (S.D. Fla.) (Seitz, J.). The resumes of Co-Lead Counsel are attached to the Pearlman

The skill and experience demonstrated by counsel here also supports the appointment of class counsel under Fed. R. Civ. Pro. 23(g). Under this provision, recently added to the Federal Rules, a court is required to consider the following when appointing class counsel: (1) the work counsel has done in identifying or investigating potential claims in the action, (2) counsel's experience in handling class actions, other complex litigation, and claims of the type asserted in the action, (3) counsel's knowledge of the applicable law, and (4) the resources counsel will commit to representing the class. The court may also consider "any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class." Noble v. 93 University Place Corp., 224 F.R.D. 330, 339-40 (S.D.N.Y. 2004) (citing Rule 23(g)(1)(C)(I)).

Here, the same evidence proffered by Plaintiff's counsel in support of their adequacy under 23(a)(4) also strongly attests to their qualification under 23(g). See Jones v. Ford Motor Credit Co., No. Civ. 8330, 2005 WL 743213, at *26 (S.D.N.Y. Mar. 31, 2005) (the test set out by 23(g) "largely incorporates the adequacy standards developed" under 23(a)(4)). In addition to Plaintiff's counsel's significant experience in litigating complex pharmaceutical antitrust actions, as discussed above, counsel also amply demonstrated their willingness to commit significant resources to investigate and prosecute the instant action. As discussed more fully below in connection with the proposed Settlement, Plaintiff's counsel aggressively pursued this case through over a million pages of document discovery, dozens of depositions, multiple dispositive motions and the mediation and settlement process that now brings them before the Court. Notably, the expense for these efforts has, to date, been borne entirely by Plaintiff's counsel. See Velez v. Majik Cleaning Service, Inc., No.

Declaration, submitted in support of Plaintiff's motion for class certification, as Exhibits "D" and "E," respectively.

03 Civ. 8698, 2005 WL 106895, at *5 (S.D.N.Y. Jan. 19, 2005) (noting that class counsel "has agreed to advance all costs of this litigation" on contingent basis).

This demonstration of commitment clearly qualifies Plaintiff's proposed Class counsel, Garwin Gerstein & Fisher LLP and Cohen, Milstein, Hausfeld & Toll PLLC to be appointed under Rule 23(g). See, e.g. Noble, supra, 224 F.R.D. at 340 (S.D.N.Y. 2004) (noting class counsel's work in discovery and in "identifying or investigating potential claims"); Fogarazzao v. Lehman Bros., Inc., No. 03 Civ. 5194, 2005 WL 1802851, at *5 (S.D.N.Y. Jul. 29, 2005) (noting that class counsel "has actively represented the purported class throughout [the] litigation.").

B. The Requirements of Rule 23(b)(3) Are Satisfied

Rule 23(b)(3) requires (1) that the Court find that common questions of law or fact predominate over individual questions; and (2) that a class action is superior to other available methods of adjudication. The requirements of Rule 23(b)(3) are satisfied here.

1. Predominance

The predominance requirement is readily met where, as here, a common nucleus of anticompetitive conduct is at the core of all Class members' claims. See, e.g., Amchem, 521 U.S. at 625 ("Predominance is a test readily met in certain cases alleging . . . violations of the antitrust laws."); Jennings Oil, 80 F.R.D. at 130 ("Where an antitrust conspiracy has been at issue, courts have tended to find that common questions predominated despite the existence of individual questions."). Plaintiff need only make a threshold showing that common or "generalized proof" will predominate at trial with respect to the essential elements of their antitrust claims. See NASDAQ, 169 F.R.D. at 517; In re Indus. Diamonds Antitrust Litig., 167 F.R.D. 374, 381 (S.D.N.Y. 1996); In re Domestic

Air Transp. Antitrust Litig., 137 F.R.D. 677, 685 (N.D. Ga. 1991); see also Mercedes, 213 F.R.D. at 190; Cardizem, 200 F.R.D. at 346.

Here, as Plaintiff previously argued, identical evidence would have been utilized to prove each of the elements of Plaintiff's and absent Class members' antitrust claims, including proof of Defendants' alleged antitrust violations, proof of antitrust impact, and proof of damages. See Class Brf. at 15–24; In re Linerboard Antitrust Litig., 305 F.3d 145, 151–54 (3d Cir. 2002); Mercedes, 213 F.R.D. at 186–87. Proof of these elements would be decidedly and predominately common.

2. *Superiority*

“The superiority requirement asks the court ‘to balance, in terms of fairness and efficiency, the merits of a class action against those of ‘alternative available methods’ of adjudication.’” In re Prudential Ins. Co. of Am. Sales Practices Litig., 148 F.3d 283, 316 (3d Cir. 1998) quoting Georgine v. Amchem Products, Inc., 83 F.3d 610, 632 (3d Cir. 1996). Here, class certification is clearly more efficient than the separate litigation of numerous separate claims. See Id. at 315–16; O’ Keefe v. Mercedes-Benz USA, LLC, 214 F.R.D. 266, 293 (E.D. Pa. 2003); see also Relafen, 218 F.R.D. at 343–344; Buspiron, 210 F.R.D. at 59. Finally, the Court need not inquire “whether the case, if tried, would present intractable management problems” because the present request is for a “settlement-only class certification,” and the proposed settlement eliminates the trial. Amchem, 521 U.S. at 620.

III. **THE COURT SHOULD GRANT PRELIMINARY APPROVAL OF THE PROPOSED SETTLEMENT**

Rule 23(e)(1) of the Federal Rules of Civil Procedure provides:

- (A) The court must approve any settlement, voluntary dismissal,

or compromises of the claims, issues or defenses of a certified class.

- (B) The court must direct notice to all class members who would be bound by a proposed settlement, voluntary dismissal, or compromise.

See Fed. R. Civ. P. 23(e)(1)(A) - (e)(1)(B).

As stated above, approval of class action settlements involves a two-step process. In step one, the Court considers whether to approve the settlement preliminarily for purposes of communicating the terms of the settlement to the proposed class. See MANUAL FOR COMPLEX LITIGATION (THIRD) §30.41 at 236–37 (1995) (“Manual”); In re General Motors Corp. Pick-Up Truck Fuel Tank Prods. Liability Litig., 55 F.3d 768, 785 (3d Cir.), cert. denied, 516 U.S. 824 (1995) (“GM Pick-Up Truck”) (“Before sending notice of the settlement to the class, the court will usually approve the settlement preliminarily. This preliminary determination establishes an initial presumption of fairness.”). In the second step, after notice to the class and provision of an opportunity for each class member to exclude itself, or object to the proposed settlement or otherwise be heard, the Court will determine whether the settlement is fair, reasonable, and adequate and whether the settlement should be finally approved under Fed. R. Civ. P. 23(e).¹³ Manual, at 237–38; In re NASDAQ Market-Makers Antitrust Litig., 176 F.R.D. 99, 102 (S.D.N.Y. 1997) (“NASDAQ II”); Grice v. PNC Mortg. Corp. of Am., No. 97 Civ. 3084, 1998 WL 350581, at *2 n.1 (D. Md. May 21, 1998); In re Ampicillin Antitrust Litig., 526 F. Supp. 494, 496 (D. D.C. 1981). The 2003 Amendments to Rule 23 did not change this bifurcated procedure. See, e.g., Varacallo v.

¹³ As provided in the Settlement Agreement and a confidential Letter Agreement, if Class members with total purchases of Remeron® exceeding a certain confidential amount exclude themselves from the Class, Defendants may terminate or modify the Settlement.

Massachusetts Mut. Life Ins. Co., 226 F.R.D. 207, 219-20 (D.N.J. 2005); In re Auto. Refinishing Paint Antitrust Litig., MDL No. 1426, 2004 WL 1068807, at *1-2 (E.D. Pa. May 11, 2004) (“Automotive Refinishing”).

Accordingly, in considering whether to grant preliminary approval, the Court is *not* required at this point to make a final determination of the adequacy of the Settlement or to delve extensively into the merits of the Settlement. See Automotive Refinishing, 2004 WL 1068807, at *1-2 (distinguishing between preliminary approval and final approval) citing MANUAL FOR COMPLEX LITIGATION (FOURTH) § 21.632 (2004). Both of these inquiries are reserved for the final approval stage. Id. Nor will any Class member’s substantive rights be prejudiced by preliminary approval, since preliminary approval is solely to obtain authority for notifying the Class of the terms of the Settlement and to set the stage for the final approval of the Settlement. Id.; see also Armstrong v. Bd. of Sch. Dirs. of City of Milwaukee, 616 F.2d 305, 314 (7th Cir. 1980) (overruled in part on other grounds); Berry v. Sch. Dist. of City of Benton Harbor, 184 F.R.D. 93, 97 (W.D. Mich. 1998); Alaniz v. California Processors, Inc., 73 F.R.D. 269, 273 (N.D. Cal. 1976); 4 Herbert Newberg & Alba Conte, NEWBERG ON CLASS ACTIONS § 11.25 (4th ed. 2002) (“Newberg”). “If the preliminary evaluation of the proposed settlement does not disclose grounds to doubt its fairness or other obvious deficiencies . . . and [the settlement] appears to fall within the range of possible approval, the court should direct that notice” issue and should schedule a final approval hearing. Manual § 30.41; Automotive Refinishing, 2004 WL 1068807, at *2 (citations omitted). Thus, if a proposed settlement could possibly be approved and it appears to be the product of informed, arm’s-length negotiations, it should be approved for purposes of setting the Fairness Hearing and notifying the Class. See NASDAQ, 176 F.R.D. at 102.

Courts generally consider several factors in determining whether a proposed settlement falls within the range of possible approval and thus should be preliminarily approved. As articulated by the Third Circuit in GM Pick-Up Truck, 55 F.3d at 781, a court will approve a class action settlement *preliminarily* if it appears capable of possible final approval and the court finds that: (1) the negotiations leading to the proposed settlement occurred at arm's length; (2) there was sufficient discovery in the litigation for the plaintiff to make an informed judgment on the merits of the claims; (3) the proponents of the settlement are experienced in similar litigation; and (4) only a small fraction of the class objected. *Id.* at 785; *see also* Newberg, § 11.41; City of Detroit v. Grinnell Corp., 495 F.2d, 448, 462-63 (2d Cir. 1974) (abrogated in part on other grounds); Hanlon v. Chrysler Corp., 150 F.3d 1011, 1026-28 (9th Cir. 1998); Armstrong, 616 F.2d at 314 (overruled on other grounds); Berry, 184 F.R.D. at 97.

The proposed Settlement here easily satisfies this test.

A. The Proposed Settlement Is Substantial

The proposed \$75 million cash Settlement is substantial in both absolute terms and in light of the particular facts and circumstances of this litigation. The Plaintiff's expert economist, who has served in a similar capacity in several analogous class cases (involving allegations and computations of damages due to delayed generic competition), has estimated in reports exchanged in the litigation that, under certain assumptions as to what would have occurred in the "but for" world, the Settlement represents a very substantial percentage of the total amount the Class was overcharged. The propriety of the assumptions used by Plaintiff's expert as well as Defendants' experts was thoroughly debated during the course of the litigation, and during the mediation and settlement process. The recovery represented by the Settlement constitutes a substantial proportion of total damages

sustained by the Class. The above showing is clearly more than sufficient to “establish an initial presumption of fairness” of the proposed consideration of the Settlement. GM Pick-Up Truck, 55 F.3d at 785.

**B. The Proposed Settlement Is The Product Of Good Faith,
Extensive, Arm’s-Length Negotiations**

The proposed Settlement resulted from extensive arm’s-length negotiations undertaken in good faith between Plaintiff, Plaintiff’s counsel, and Defendants over a period of more than a year. The settlement negotiations included two separate mediation processes, the first conducted by Judge Nicholas Politan in January, 2004, the second conducted by Professor Eric Green over several sessions in 2005. All mediations were conducted under the auspices of this Court. The parties have also participated in several settlement conferences with the Court directly. All mediation sessions and settlement negotiations actively involved Plaintiff’s counsel, Plaintiff and counsel for Defendants. The parties scrutinized the strengths and weaknesses of the pending claims, including consideration of, among other issues, liability, causation and damages. The parties engaged in intensive bargaining over the merits and the value of Plaintiff’s claims, and the merits of Defendants’ defenses. Because of the extensive, arm’s-length bargaining involved, there is no issue (or even a suggestion) of any collusive aspect to the proposed Settlement.

**C. There Was More Than Sufficient Discovery And Investigation
for Counsel for the Class to Make an Informed Decision**

Discovery in this case spanned more than a year, is complete, and has been extensive. This discovery included the entire record in the underlying patent litigation, numerous interrogatories and document requests, as well as third-party subpoenas to pharmaceutical manufacturers and consultants to the pharmaceutical industry. In all, Plaintiff reviewed and analyzed well over one million pages

of documents made available by Defendants, the other parties to this litigation, and various non-parties. Plaintiff and its experts also obtained (from Defendants, other parties, non-parties and independent data storage companies) and analyzed electronic sales databases. At the same time, Plaintiff answered extensive interrogatories and collected and produced voluminous records, and both Plaintiff and the parties' experts have been extensively deposed. As a result of this effort, the facts concerning Defendants' potential liability are extremely well developed.

Armed with this written and electronic discovery, counsel for the Direct Purchaser Class deposed numerous current and former executives and employees of Defendants. Plaintiff also deposed third parties with knowledge of and information regarding the events described in the Amended Complaint. Counsel for the Direct Purchaser Class also retained and worked with expert witnesses in evaluating scientific and economic issues relating to liability and damages. These experts produced numerous reports, some of which have been submitted to the Court and the mediators. Plaintiff and its experts also reviewed, analyzed, and responded to reports served by Defendants' experts. As a result, issues relating to liability and damages have been developed sufficiently for counsel for the Direct Purchaser Class to make an informed decision regarding the proposed Settlement.

D. The Proponents Of The Settlement Are Highly Experienced In Antitrust Litigation

The Class is represented by lawyers who have extensive antitrust class action experience. Plaintiff's counsel and the other firms representing the Direct Purchaser Class are on the forefront of antitrust litigation and complex litigation generally, as well as litigation pertaining to the pharmaceutical industry specifically. Thus, Plaintiff's counsel are well versed in both prosecution

and settlement of this type of litigation. See Class Brf. at 14.

Accordingly, Plaintiff counsel's recommendations are entitled to great weight. Indeed, courts have repeatedly and explicitly deferred to the judgment of experienced counsel who have conducted arm's-length negotiations in approving proposed class settlements. See, e.g., Varacallo, 226 F.R.D. at 240 ("Class Counsel's approval of the Settlement also weighs in favor of the Settlement's fairness.") (citations omitted); Blank v. Talley Indus., Inc., 64 F.R.D. 125, 132 (S.D.N.Y. 1974) (a factor "entitled to substantial weight is that the settlement bears the imprimatur of seasoned and experienced counsel"); Fisher Bros. v. Phelps Dodge Indus., Inc., 604 F. Supp. 446, 452 (E.D. Pa. 1985) ("the professional judgment of counsel involved in the litigation is entitled to significant weight"); In re Coordinated Pretrial Proceedings in Antibiotic Antitrust Actions, 410 F. Supp. 659, 667 (D. Minn. 1974) ("[t]he recommendation of experienced antitrust counsel is entitled to great weight").¹⁴ The presumption in favor of such settlements reflects the understanding that vigorous, skilled negotiation protects against collusion and advances the fairness interests of Rule 23(e).

E. Initial Reaction Of Class Members Is Fully Supportive Of The Settlement

Although formal notice of settlement has not yet been sent, counsel for Plaintiff has spoken with Plaintiff, who was actively involved in the negotiations, and the three most substantial members of the Class (as measured by purchases), who also actively participated in the mediation process, to describe the proposed Settlement. Plaintiff and those Class Members contacted have indicated that they view the proposed Settlement favorably and no member of the Class has voiced an objection

¹⁴ See also Stewart v. Rubin, 948 F. Supp. 1077, 1099 (D.D.C. 1996), aff'd, 124 F.3d 1309 (D.C. Cir. 1997); In re Lease Oil Antitrust Litig. (No. II), 186 F.R.D. 403, 424-425 (S.D. Tex. 1999); In re Domestic Air Transp. Antitrust Litig., 148 F.R.D. 297, 312-13 (N.D. Ga. 1993); Manual § 30.42; 4 Newberg, § 11.41.

to date. Furthermore, each Class member will have an opportunity to make any objection to the proposed Settlement prior to the Fairness Hearing, or to exclude itself.

Accordingly, based on the above factors, this Court should grant preliminary approval of the proposed Settlement.

IV. THE COURT SHOULD APPROVE THE PROPOSED FORM AND MANNER OF NOTICE AND THE PROPOSED SCHEDULE LEADING UP TO THE FAIRNESS HEARING

Rule 23(e)(1)(B) provides that “[t]he court must direct notice in a reasonable manner to all class members who will be bound by a proposed settlement. . . .” The purpose of the notice is to “afford members of the class due process which, in the context of the Rule 23(b)(3) class action, guarantees them the opportunity to be excluded from the class action and not be bound by any subsequent judgment.” Peters v. National R.R. Passenger Corp., 966 F.2d 1483, 1486 (D.C. Cir. 1992) citing Eisen, 417 U.S. at 173-74; see also Gottlieb v. Wiles, 11 F.3d 1004, 1012-13 (10th Cir. 1993) (overruled in part on other grounds) (notice must fairly inform class members of the settlement and their options). The proposed notice program clearly meets this standard.

Annexed to the Settlement Agreement as Exhibit “B”, are a proposed form of direct mail and publication notice (the “Notices”). Plaintiff proposes mailing the direct mail notice to each entity that purchased Remeron® directly from Organon at any time during the period January 16, 2002 through and including August 24, 2005, at its last known address (for whom such address is known), and to publish the summary notice in an industry trade publication, *The Pink Sheet*, likely to reach a substantial percentage of the Class. Given that Defendants have produced certain sales records in this case, including detailed customer lists, and will supplement these records in connection with the Settlement process, it is highly likely that the direct mail method will be sufficient to reach all or

substantially all Class members, and thus publication will act solely as a fail-safe, back-up measure.

In any event, publication in the proposed periodical will also reach all or nearly all of Class members. For instance, *The Pink Sheet* describes itself as follows on its web site:

Founded in 1939, "The Pink Sheet" provides in-depth coverage of the prescription pharmaceutical industry. Known as "The Bible" to the prescription pharmaceutical industry, this specialized weekly publication covers regulatory activities of FDA, FTC and CMS; Congress; industry news, such as mergers and acquisitions, new product introductions and executive changes; and financial news, such as companies' sales and earning performance and stock activity. The publication covers research, manufacturing, distribution and the retail sector.

The Pink Sheet has also been approved as the form of notice in past pharmaceutical antitrust settlements. See, e.g. Oncology & Radiation Assocs., P.A. v. Bristol-Myers Squibb Co., No. Civ. A. 1:01 CV 02313, 2003 WL 21087979, at *2 (D.D.C. May 13, 2003). In addition, Co-Lead Counsel for the Direct Purchaser Class will post the Settlement Agreement and the notices on their firm websites at www.garwingerstein.com and www.cmht.com, respectively.

Accordingly, the form and manner of notice Plaintiff proposes will satisfy both the notice requirements of Rule 23(e), and due process requirements which must be met in order to bind each member of the Class. See Grimes v. Vitalink Communications Corp., 17 F.3d 1553, 1560 (3d Cir. 1994) (Direct mail notice found sufficient under Rule 23); Galloway v. Southwark Plaza Ltd. P'ship, No. 01-835, 2003 WL 22657200, at *2 (E.D. Pa. Oct. 27, 2003) (same); see also Mullane v. Central Hanover Bank & Trust Co., 339 U.S. 306 (1950); In re PaineWebber Ltd. P'ships Litig., 171 F.R.D. 104, 124 (S.D.N.Y. 1997); Twigg v. Sears, Roebuck & Co., 153 F.3d 1222, 1226 (11th Cir. 1998).

In addition, the content of the Notices satisfy the requirements of Rule 23(e). The proposed Notices provide a description of the Class, the procedural status of the litigation, a summary of the

plan of allocation, and advise Class members of their rights under Rule 23(b)(3), including the right to be heard as to the reasonableness and fairness of the Settlement. The Notices also set forth the significant terms of the Settlement and the total amount of money Defendants have agreed to pay to the Direct Purchaser Class. Finally, they outline the Court approval process for the proposed Settlement, counsel's request for fees and reimbursement of expenses,¹⁵ and the proposed incentive award of \$60,000 for plaintiffs LWD and Meijer, Inc. (to compensate them for the substantial efforts made on behalf of the Class including LWD's President submitting to deposition, and his active involvement in the several mediation sessions).¹⁶

Under the circumstances, the Notices fairly describe the proposed Settlement and its legal significance as well as that of the Class Action, thereby satisfying the notice requirements of Rule 23(e). See, e.g., Twigg, 153 F.3d at 1227 (“[The notice] must also contain an adequate description of the proceedings written in objective, neutral terms, that, in so far as possible, may be understood by the average absentee class member[.]”), quoting In re Nissan Motor Corp. Antitrust Litig., 552

¹⁵ Direct Purchaser Class Counsel shall, pursuant to the proposed schedule outlined below, submit an application for attorneys' fees and expenses to be reimbursed out of the settlement proceeds.

¹⁶ Courts routinely grant incentive awards to class representatives. Most notably, this Court has done so in connection with the approval of the proposed settlement of the Remeron End-Payor antitrust cases. See Preliminary Approval Order, dated Jan. 25, 2005, In re Remeron End-Payor Antitrust Litig., Master File No. 02-cv-2007 (D. N.J. 2002); In re Domestic Air Trans. Antitrust Litig., 148 F.R.D. at 297 (“The Court finds that incentive awards are appropriate to recognize the efforts of the representative plaintiffs to obtain recovery for the class.”); Lease Oil, 186 F.R.D. at 449 (recognizing that class representatives were entitled to additional compensation for their time and effort); In re Plastic Tableware Antitrust Litig., No. 94 CV 3564, 1995 WL 723175, at *2 (E.D. Pa. Dec. 4, 1998) (“Payments to class representatives may be considered a form of restitutionary relief within the discretion of the trial court. ... They may also be treated as a reward for public service and for the conferring of a benefit on the entire class.”).

F.2d 1088 (5th Cir. 1977); Bennett v. Behring Corp., 96 F.R.D. 343, 353 (S.D. Fla. 1982) (“It is not the function of the settlement notice to fully inform the class of all the details of the settlement, but merely to put class members on notice of the general parameters of the settlement and to inform them of where information as to specifics may be obtained.”).

As set out in the Certification, Plaintiff proposes the following schedule for completing the approval process:

- a. Within 20 days of entry of the preliminary approval order: Dissemination of notice to the Class (via both proposed methods) on or before this date;
- b. 50 days from entry of preliminary approval order: Deadline for opting out of the Class or objecting to the Settlement;
- c. One week after opt-out deadline: Submission of Plaintiff’s Counsel’s motion for final approval of the Settlement, application for attorneys’ fees and expenses and application for an incentive award for Plaintiff¹⁷; and
- d. Two weeks after opt-out deadline, or such later date as results from the use of the dispute resolution process in connection with Paragraph 14 of the Settlement Agreement: The Fairness Hearing.

IV. CONCLUSION

For the foregoing reasons, the Court should preliminarily approve the proposed Class Action Settlement, appoint Class Counsel, approve the proposed forms of notice and the proposed schedule

¹⁷ This date is subject to extension in the event that, in the judgment of counsel for either Plaintiff or Defendants, additional time is required to complete the calculations and/or dispute resolution process provided for in connection with Paragraph 14 of the Settlement Agreement.

proposed schedule (or any other schedule satisfactory to the Court), and certify the proposed Class. A proposed form of Order is attached to the Settlement Agreement as Exhibit "A".

Dated: August 30, 2005

Respectfully submitted,

By: /s/ Peter S. Pearlman

Peter S. Pearlman
A Member of the Firm
Liaison Counsel in the Consolidated
Direct Purchaser Actions

Bruce E. Gerstein
Noah Silverman
Adam Steinfeld
GARWIN GERSTEIN &
FISHER, LLP
1501 Broadway, Suite 1416
New York, NY 10036
Tel: (212) 398-0055
Fax: (212) 764-6620

*Co-Lead Counsel in the Consolidated
Direct Purchaser Actions*

Linda Nussbaum
Cathy Torell
COHEN, MILSTEIN, HAUSFELD &
TOLL, P.L.L.C.
825 Third Avenue
New York, NY 10022-7519
Tel: (212) 838-7797
Fax: (212) 838-7745

*Co-Lead Counsel in the Consolidated
Direct Purchaser Actions*

Daniel Berger
Eric L. Cramer
Peter Russell Kohn
Neill Clark
BERGER & MONTAGUE, P.C.
1622 Locust Street
Philadelphia, PA 19103
Tel: (215) 875-3000
Fax: (215) 875-4604
Counsel for Direct Purchaser Class

John Gregory Odom
Stuart Des Roches
Randall Acree
ODOM & DES ROCHES, LLP
Suite 2020, Poydras Center
650 Poydras Street
New Orleans, LA 70130
Tel: (504) 522-0077
Fax: (504) 522-0078
Counsel for Direct Purchaser Class

Michael F. Heim
Russell H. Chorush
Robert Gray
CONLEY, ROSE & TAYON, P.C.
600 Travis, Suite 1800
Houston, Texas 77002
Tel: (713) 238-8000
Fax: (713) 238-8008
Counsel for Direct Purchaser Class

David P. Smith
**PERCY, SMITH, FOOTE
& GADEL, L.L.P.**
720 Murray Street
P.O. Box 1632
Alexandria, LA 71309
Tel: (318) 445-4480
Fax: (318) 487-1741
Counsel for Direct Purchaser Class